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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,755	10/24/2001	Peter William Taylor	4-20251C/C1C1/MA2102	5831

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/001,755

Applicant(s)

TAYLOR ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-34 is/are pending in the application.
- 4a) Of the above claim(s) 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

RE: Taylor et al

Priority Date: 8 December 1994

1. The amendment filed 4/23/2004 is acknowledged and entered into the record. Accordingly, no claims have been canceled, added, or amended.
2. Claims 22-34 are pending, claim 34 is withdrawn as being drawn to a non-elected invention. Applicant is reminded to cancel all claims drawn to non-elected subject matter.
3. Claims 22-33 are therefore examined on the merits.

Claim Rejections Maintained - 35 USC § 112, 2nd paragraph

4. The rejection of claims 22-33 under 35 USC 112, 2nd paragraph as being indefinite is maintained for the reasons of record. Applicant argues that one of skill in the art would readily understand the metes and bounds because the term was well established and readily used in the art. Applicant also refers to foreign EP documents to support the assertion that the terms are well established and used in the art. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. The terms BD and BDBB as stated before are laboratory designated terms and without specifically defining the meaning of the term one of skill in the art cannot readily decipher the distinction between the BD of the instantly claimed invention from a BD as disclosed by Sabbadin A et al (Dev Comp Immunol. 1988 Fall;12(4):737-47). As such, the use of laboratory designations only to identify a particular molecule renders the claims indefinite because different laboratories

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may use the same laboratory designations to define completely distinct molecules. The rejection can be obviated by amending the claims to specifically and uniquely identify BD or BDBB, for example, by SEQ ID NO. and function of BD or BDBB. Therefore the rejection under 35 USC 112, 2nd paragraph is maintained.

Claim Rejections Maintained - 35 USC § 103

5. The rejection of claims 22-33 under 35 USC 103(a) as being obvious over Fidler *et al* (EP 0 331635A2) in view of Weiner *et al* (WO 91/01719) is maintained for the reasons of record. Applicants appear to argue that the combination of the references do not provide a reasonable expectation of success in creating the composition of the instant invention, because Fidler *et al* teaches a combination of two phospholipids, while the instantly claimed invention is drawn to “cholesterol”, and two phospholipids.

Further applicant argues that Weiner *et al* does not teach a composition that is useful for *intravenous* administration, instead, Weiner *et al* teach a topical formulation. In addition, applicant argues that the three lipid components have critical temperature transitions, which is crucial for the formulation of an “injectable formulation”. Applicant’s arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

In response to the arguments raised by the applicant, it was well established at the time the invention was made that one of ordinary skill in the art would appreciate that the addition of “cholesterol” to the formulation would make for a more stable liposomal composition. The addition of cholesterol has been long established as a

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means to stabilize a liposome to increase the circulation time within the circulatory system. This is demonstrated by Yau-Young A (WO 87/04592), wherein it is taught that the addition of cholesterol to a liposome increase stability and increases the time a lipid is left in circulation before clearance from the system (see page 8). Thus the addition of "cholesterol" to the two phospholipids is obvious and one of skill in the art would be motivated to do so because the liposome would benefit from increased stability and circulation time. In addition, motivation also comes from Weiner *et al*, wherein it is stated that "liposome type, size, lipid composition and charge affect the degrees of drug entrapment or encapsulation, the drug's location in the liposome, stability..." (see page 14). Hence, given the fact that Yau-Young *et al* and Weiner *et al* recognize the importance of lipid composition for stability, one of skill in the art at the time the invention was filed (i.e. 1994) would also know that the addition of a stabilizing component such as cholesterol would only improve the stability of the composition.

Lastly, with regard to applicant's arguments concerning "intravenous" administration and "injectable formulation" the arguments have been carefully considered but are not deemed persuasive because arguments that rely on a particular distinguishing features are not persuasive when those features are not recited in the claims. Narrow limitation contained in the specification cannot be inferred in the claims where the elements not set forth in the claims are linchpin of patentability. See *In re Philips Industries, Inc. v. State Stove & Mfg. Co.*, 522 F.2d 1137, 186 USPQ 458 (CA6 1975), 237 PTJA A-12. While the claims are to be interpreted in light of the specification, it does not follow that limitations from the specification may be read into

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claims. On the contrary, claims must be interpreted as broadly as their terms reasonably allow. See *Ex parte Oetiker*, 23 USPQ2d 1641 (BPAI, 1992). Applicant is reminded that the claims define the subject matter of his invention and that the specification cannot be relied upon to read limitations into the claims. Furthermore, because the arguments regarding the criticality of the phase transition temperature have not been specifically refuted as being absent from *Weiner et al* or *Fidler et al*, and because the specification or the arguments of record have not provided any objective evidence of its criticality, or the discovery of any unexpected results, the arguments are not persuasive because they have not been substantiated by any facts or showing of evidence, thus these arguments cannot take the place of factual supportive objective evidence. *In re Huang*, 100 F3d 135,139-40, 40USPQ2d 1685, 1689 (Fed. Cir. 1996).

Therefore the rejection under 35 USC 103(a) as being obvious is maintained.

Conclusion

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
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July 21, 2004



GARY NICKOL
PRIMARY EXAMINER